

Memo

Please share as appropriate.

To: North Dakota Clinical Laboratories
From: Christie Massen (clmassen@nd.gov)
Section Chief, Division of Laboratory Services
Date: 11/30/2020
Re: Individualized FDA EUA SARS CoV-2 Molecular Information

The North Dakota Department of Health Division of Laboratory Services, strives to continue its service to the citizens of North Dakota. The following includes a list of the most used SARS CoV-2 Molecular tests offered:

- Abbott Real-Time SARS CoV-2 PCR
- Hologic Aptima SARS CoV-2 Transcription Mediated Amplification
- ThermoFisher TaqPath COVID-19 Combo Kit Real-Time PCR

Additional SARS CoV-2 Molecular tests offered:

- Cepheid Xpert Express SARS CoV-2 Real-Time PCR
- BioFire Respiratory Panel 2.1

For the FDA EUA SARS CoV-2 PCR complete list along with the associated healthcare fact sheets, patient fact sheets, and additional documents, please refer to their website:

<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas>

For the updated Directory of Services and/or Test Request Form, please refer to our website:

<http://www.ndhealth.gov/microlab/>

CLIA ID Number: 35D0691722

If you have any questions, please contact our facility for the recommended guidance.

We are here to serve you!